REMARKS

Claims 1 – 10, 12 – 19, and newly added claim 23 are now pending in the application. All pending claims have been rejected.

REJECTION UNDER 35 U.S.C. §101

Claims 1 – 10 and 12 – 19 are rejected under 35 U.S.C. § 101 on the grounds that the claims lack specific and substantial utility. Applicant respectfully traverses.

The claims of the invention pertain to novel, time-saving methods of isolating a DNA fragment with known utility. Such methods are useful research tools for those involved in the fields of genetics and molecular biology. The specification, in page 12, discloses that this novel method of isolating an intact clone of the target nucleic acid fragment has useful application in cloning a gene by expression library; cloning by homology, Southern blot identification, and the study of polymorphism. Indeed, in examples 4 and 5 of the specification, the invention is particularly disclosed as a tool to study human polymorphism.

Furthermore, the invention is a novel and more efficient research tool for the study of human polymorphism. The disclosure describes several time-saving processes for isolating such an intact clone of the target nucleic acid fragment which are advantageous over prior art techniques available for such studies. The specification discusses the techniques in the prior art which require several months to complete, contrasted with the invention's method, which takes three days (pg. 23). Moreover, the present invention offers a technique that is less costly than those of the prior art (page. 21). With respect to the invention's application to studying human polymorphism and genetic diseases, the specification on pages 28-29 further teaches that the invention makes it possible to very quickly localize the origin of a genetic

disease by analysis of the various members of a family harboring a genetic disease. Because the processes disclosed in the specification are more efficient and less costly than those in the prior art, an immediate a tangible benefit is provided to the public in "real world" uses.

The Examiner remains troubled by the apparent lack of guidance toward the suitable "known characteristics" of the target DNA fragment. Applicant respectfully contends that the utility of this invention is not adversely affected by the guidance of such "known characteristics". The principle benefit of the invention is its universal applicability. The invention is not only applicable to a limited range of DNA fragments. Indeed, the invention operability does not depend on particular characteristics of the known fragments. Those skilled in the art who wishes to employ the invention in their research can readily supply identity nucleic acid fragments of interest because those will be the very nucleic acid fragments that the scientist was interested in. No further research is needed to identify "known characteristics" that would be suitable for the present invention. Those skilled in the art can readily apply the claimed processes to their existing research to save time and enhance efficacy. Claims 1 and 16 have been amended to particularly point out that those skilled in the art are to provide the "known characteristic" without altering the scope of the claims.

The Examiner is likewise concerned with the lack of guidance as to specific screening methods to be used in connection with the invention. Applicant respectfully contends that any screening methods known in the art are applicable to the invention. These methods are well known and described in publications such as "Molecular Cloning: A Laboratory Manual" by Joseph Sambrook et al. Those skilled in the art will be able to select among these techniques to detect the presence of intact target fragments among the monodigested libraries. Therefore,

the lack of guidance in the specification does not pose an insurmountable hurdle to those skilled in the art who wish to practice the invention.

For the above-stated reasons, neither the lack of specificity of the target "known characteristics" nor of the screening methods for detection prohibit the use of the invention. Indeed, the universal applicability of this technique confers immediate benefits, namely the saving of time and money, to the entire fields of genetics and molecular biology. Applicant respectfully requests the withdrawal of the rejection based on 35 U.S.C. §101.

REJECTION UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Claims 1 – 10, 12 – 19 are rejected on the ground that one skilled in the art would not know how to use the claimed invention in view of the alleged lack of specific asserted utility. In addition, the Examiner finds that those skilled in the art would not be able to make or use the invention because of the lack of specificity in suitable nucleic acid fragments with known characteristics and screening methods. Applicant respectfully traverses.

Applicant asserts that those skilled in the art will, after reading the instant disclosure, readily understand that the invention is an improved research tool that is broadly applicable in the fields of genetics and molecular biology. The breadth of the claims reflects the universal applicability of the invention. As argued above, scientists engaged in research in the fields of genetics and molecular biology will be able to identify nucleic acid fragments of interest. Likewise, they will be able to construct vectors suitable for use in the invention given the guidance provided in page 5-6 of the specification. Moreover, skilled artisans may employ suitable screening techniques since such techniques are well known in the prior art. Applicant asserts that the kinds of experimentation the scientist may be required to conduct – determining the target nucleic acid fragments of interest and determining the suitable screening techniques to detect their presence – are the kinds of decisions that scientists in these fields engage in daily.

Accordingly, Applicant submits that the disclosure fully enables the claimed invention.

REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH

The Examiner rejects the processes Claims 1-10, 12-19 of this invention because "there is a step missing between (b) and (d)," namely, that the screening steps suitable for the

invention is not laid out. Applicant disagrees with the necessity of reciting those steps, because those skilled in the art are familiar with the screening protocols to detect the presence of a nucleic acid fragment with a known characteristic. These techniques are well-known and well-described in the prior art. The choice of the proper technique depends on the characteristic of interest of the clone fragment and therefore is a choice that one skilled in the art will be readily able to supply in using this invention.

To the extent that the perceived indefiniteness results from the breadth of the claims, Applicant asserts that he is entitled to claims as broad as the prior art and the application disclosure will allow. *In re Rasmussen*, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). If the scope of the subject matter embraced by the claims is clear, and if Applicant has not otherwise indicated that the invention is to be of scope different from that defined in the claims, then the claims comply with § 112, second paragraph. The breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 169 U.S.P.Q. 597, 600 (C.C.P.A. 1971). A claim may be broader than the specific embodiment disclosed in the specification and still be definite. *Ex parte Hendrickson*, 42 U.S.P.Q. 634 (Pat. Off. Bd. App. 1939).

To the extent that this rejection represents a breadth of claim issue, Applicant maintains that he is entitled to claims as broad as the prior art and the application disclosure will allow. *In re Rasmussen*, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). If the scope of the subject matter embraced by the claims is clear, and if Applicant has not otherwise indicated that the invention is to be of scope different from that defined in the claims, then the claims comply with § 112, second paragraph. The breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 169 U.S.P.Q. 597, 600 (C.C.P.A. 1971). A claim may be broader than the specific

embodiment disclosed in the specification and still be definite. *Ex parte Hendrickson*, 42 U.S.P.Q. 634 (Pat. Off. Bd. App. 1939).

The Examiner's objection stems from the breadth of the recitation that the monodigested libraries are screened for the presence of a nucleic acid with a known characteristic. The Examiner requires that the missing screening steps be disclosed. Applicant respectfully notes that such steps are readily known in the art and can be readily supplied by those skilled in the art. Moreover, under *Ex parte Hendrickson*, claim terminology may be broader than the specific embodiments disclosed in the specification if the terminology is otherwise clear. Those skilled in the art will readily understand "screening" to comprise necessary steps in a particular method. For example, in one illustrative screening method, performing a Southern blot and analyzing the resulting nylon member through autoradiography would be steps know to one skilled in the art. Thus, the Examiner has failed to set forth a *prima facie* case of indefiniteness. Accordingly, It is respectfully requested that the Examiner's indefiniteness rejection should be withdrawn.

CONCLUSION

In so far as the above amendments and remarks have addressed fully the Examiner's rejections, the instant application is seen to be in condition for allowance. In view of the foregoing, withdrawal of the Examiner's rejections and issuance of a Notice of Allowance of all pending claims is therefore respectfully requested.

Respectfully submitted,
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